



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0469; FRL-9387-8]

#### Diisopropyl adipate; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of diisopropyl adipate when used as an inert ingredient (solvent) in pesticide formulations applied to pre- and post-harvest crops under EPA regulations at no more than 40% in formulated products intended for mosquito control. Wellmark International submitted a petition prepared by Technology Sciences Group Inc. to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of diisopropyl adipate.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0469, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm.

3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** David Lieu, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-305-0079; email address: *Lieu.David@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.ecfr.gov/cgi-bin/text->

*idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\_02.tpl*. To access the OCSPP test guidelines referenced in this document electronically, please go to *<http://www.epa.gov/ocspp>* and select “Test Methods and Guidelines.”

*C. How Can I File an Objection or Hearing Request?*

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0469 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0469, by one of the following methods:

- *Federal eRulemaking Portal*: *<http://www.regulations.gov>*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of August 22, 2012 (77 FR 50661) (FRL-9358-9), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8031) by Wellmark International, Central Life Sciences, 1501 East Woodfield Road, Suite 200 West, Schaumburg, IL 60173. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of diisopropyl adipate (CAS Reg. No. 6938-94-9) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops only at no more than 40% in formulated products intended for mosquito control. That document referenced a summary of the petition prepared by Technology Sciences Group Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA has modified the exemption requested to include an exemption from the requirement of a tolerance for residues of diisopropyl adipate (CAS Reg. No. 6938-94-9) under 40 CFR 180.910 when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest at

no more than 40% in formulated products intended for mosquito control. The reason for these changes is explained in Unit V.

### **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in

establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for diisopropyl adipate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with diisopropyl adipate follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to

human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by diisopropyl adipate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The acute oral toxicity of diisopropyl adipate in rodents, as expressed as an LD<sub>50</sub>, ranges from 1,500 mg/kg to 8,800 mg/kg. In the guinea pig, the acute oral toxicity of diisopropyl adipate is about 6,600 mg/kg and in the rabbit, 5,000 mg/kg. In the dog, the acute oral LD<sub>50</sub> of diisopropyl adipate is greater than 8,000 mg/kg. Diisopropyl adipate is minimally irritating to the eyes and skin of rabbits.

The potential for toxicity following repeat dose exposure to diisopropyl adipate was evaluated based on toxicity studies with diisopropyl adipate as well as toxicity data on the two primary metabolites of diisopropyl adipate, adipic acid (CAS Reg. No. 124-04-9) and isopropyl alcohol (CAS Reg. No. 67-63-0). Isopropyl alcohol was previously assessed in the U.S. EPA inert reassessment document titled, Inert Reassessment – n-Propanol; CAS Reg. No. 71-23-8, dated August 24, 2005 and no end points of concern were identified. In addition, toxicity data from two structural analogues of diisopropyl adipate, dipropyl adipate and diisobutyl adipate, were also considered. These substances would be expected to have toxicological properties similar to diisopropyl adipate and can be used to supplement the available toxicity data on diisopropyl adipate. The studies summarized below were either performed with diisopropyl adipate, adipic acid, dipropyl adipate or diisobutyl adipate.

In a 5 week study, guinea pigs that were administered adipic acid orally showed no adverse effects up to doses of 1000 mg/kg/day. In a 90 day oral toxicity study, male rats were given 0, 0.1, 1 or 5% adipic acid and female rats were given 0 or 1% adipic acid. The NOAEL was 1% (1000 mg/kg/day) and a LOAEL of 5% (5000 mg/kg/day) based on growth retardation in males. In a 19 week oral toxicity study in rats, each rat was given 0, 50, 100, 200 or 400 mg adipic acid/rat/day. The NOAEL was 200 mg adipic acid/rat/day (equivalent to 1700 mg/kg/day) and the LOAEL was 400 mg adipic acid/rat/day (equivalent to 3,400 mg/kg/day) was based on slight effects on liver and irritation of the intestine. In a 33 week subchronic oral toxicity study on groups of 13-15 male and female rats at doses of 0, 400, 800 mg/rat/day or approximately 0, 1600 and 3200 mg/kg bw/day adipic acid produced a LOAEL of 400mg/rat/day (equivalent to 1600 mg/kg bw/day) based on slight liver effects and inflammation of the intestine and no NOAEL was observed. In a 3 week inhalation toxicity study, rats were exposed to 0.126 mg/L adipic acid for 6 hr periods daily for five days a week for a total of 15 exposures. No signs of toxicity were seen, blood tests gave normal values and autopsy results revealed all organs to be normal.

The mutagenic potential of adipic acid was evaluated in a Host-Mediated Assay, in an *in vivo* cytogenetics test, and a dominant lethal assay. These tests were negative.

An OECD SIDS Initial Assessment Report on Adipic Acid (2004) concluded that adipic acid was not carcinogenic in a limited two-year feeding study where groups of twenty male rats were dosed with food containing 0, 0.1, 1, 3 and 5% (equivalent to 0, 75, 750, 2250 or 3750 mg/kg/day) adipic acid, and female rats were dosed with 0%



(n=10) and 1% (n=19) adipic acid, respectively. The incidences of tumors observed in the adipic acid treated groups were observed at the same levels as in the control groups.

Developmental studies (FDRL 1972) via oral gavage using adipic acid on mice, rats, hamsters and rabbits showed no maternal or developmental toxicity. The NOAELs for mice, rats and hamsters were 263, 288 and 205 mg/kg/day, respectively. These studies were not conducted at the limit dose. However, the concern for developmental toxicity of diisopropyl adipate is low because no systemic toxicity was seen in chronic studies at doses near the limit dose. In addition, the developmental toxicity studies conducted with two analogue substances (dipropyl adipate and diisobutyl adipate) via intraperitoneal route showed no developmental toxicity at doses around 700 mg/kg/day.

An immunotoxicity study from the OECD SIDS 2004 IUCLID Data Set stated that the lymphocyte mitogenesis test was used to test for immunotoxicity in vitro. In this test lymphocytes were stimulated by a polyclonal mitogen specific for either B or T cells. Neither B nor T lymphocyte mitogenesis was inhibited by adipic acid at concentrations up to 0.3%.

There were no neurotoxicity studies available in the database. However, there were no clinical signs of neurotoxicity observed in the available studies.

There are no published metabolism studies on diisopropyl adipate specifically, but the metabolic pathways of diisopropyl adipate are proposed based on the characteristic molecular structure of diisopropyl adipate and the known metabolic pathways for structurally similar compounds. Diisopropyl adipate is a linear fatty acid diester that has an isopropyl group bound to the oxygen atom on each end of the molecule. Given these structural groups, diisopropyl adipate metabolism is almost certainly catalyzed by

carboxylesterase enzymes that are ubiquitous throughout the body to produce adipic acid plus two molecules of isopropyl alcohol.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

The rationale of the toxicological endpoints for diisopropyl adipate used for human risk assessment is as follows.

The chronic toxicity/carcinogenicity study in rats was selected for all exposure scenarios and durations for this risk assessment. The NOAEL in this study was 750

mg/kg/day. The LOAEL was 2,250 mg/kg/day based on body weight retardation. The rationale for selecting this study is as follows. The lowest NOAEL (205 mg/kg/day) in the database was observed in a developmental study in hamsters. In this study 205 mg/kg/day was the highest dose tested. This study was not selected because maternal and developmental toxicity were not observed at doses as high as 263 and 288 mg/kg/day in mice and rats, respectively. Also, in a developmental toxicity study where rats were treated via intraperitoneal injection of adipic acid esters, maternal and developmental toxicity were not observed at doses as high as 727 mg/kg/day. The developmental LOAEL was 1,211 mg/kg/day based on increased resorptions and a slight but significant increase in gross abnormalities. However, these studies are not useful for endpoint selection because they were conducted via intraperitoneal route which is not relevant for the dietary, dermal or inhalation risk assessment. Also, the 19 and 33 weeks and 2 years oral toxicity studies showed no evidence of toxicity at doses as high as 750 mg/kg/day. Therefore, the chronic toxicity study in rats with the NOAEL of 750 mg/kg/day provided a good basis for establishing the chronic reference dose (cRfD). The NOAEL is considered extremely conservative because the extrapolation from adipic acid to diisopropyl adipate was not performed in order to keep the toxicity endpoint selection more conservative. Diisopropyl adipate is a large molecular weight compound compared to adipic acid. Converting adipic acid to diisopropyl adipate in a 1 to 1 molar ratio (one molecule of diisopropyl adipate contains 1 molecule of adipic acid) would mean the NOAEL and LOAEL values would be increased proportionately to the molecular weight ratios, 230 g/mol for diisopropyl adipate and 146 g/mol for adipic acid (eg. The NOAEL of 750 mg/kg/day for adipic acid would become 1,181 mg/kg/day if converted to

diisopropyl adipate). The uncertainty factor of 100x was used for 10x intraspecies variability and 10x for interspecies extrapolation.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to diisopropyl adipate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from diisopropyl adipate in food as follows:

Because no acute endpoint of concern was identified, a quantitative acute dietary exposure assessment is unnecessary.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What we eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. The Dietary Exposure Evaluation Model (DEEM) is a highly conservative model with the assumption that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates

(Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.” (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2008-0738.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for diisopropyl adipate, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Diisopropyl adipate may be used in inert ingredients in pesticide products that are registered for specific uses that may result in outdoor residential exposures. A screening level post-application residential exposure and risk assessment was performed using high-end exposure scenarios for outdoor residential uses based on end-use product application methods and highest labeled application rates submitted for two sample product labels containing diisopropyl adipate as inert ingredients submitted by the registrant.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning

the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found diisopropyl adipate to share a common mechanism of toxicity with any other substances, and it does not produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that diisopropyl adipate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Fetal susceptibility was not observed in rats, mice, rabbits or hamsters in any of the developmental studies with adipic acid, a metabolite of diisopropyl adipate. Maternal and developmental toxicity was not observed at doses as high as 288 mg/kg/day. Also, in a developmental toxicity study in rats treated with dipropyl adipate or diisobutyl adipate, analogues of diisopropyl adipate, maternal

and developmental toxicity was not observed at  $\geq 1,130$  mg/kg/day. A 2-generation reproduction toxicity study in rodents is not available in the database. However, the concern for the lack of this study is low because maternal and offspring toxicity was not observed at or above the limit dose (at levels up to 1,211 mg/kg/day) in rats and the lack of any effects on reproductive indices in mice, rats and rabbits. In addition, there was no evidence of histopathological changes in reproductive organs in chronic toxicity studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X SF.

That decision is based on the following findings:

i. The toxicity database for diisopropyl adipate includes several subchronic and chronic studies, several developmental toxicity studies, a chronic/carcinogenicity study, a mutagenicity study, and an immunotoxicity study. In addition, the metabolism of structurally similar compounds has been characterized, and that data supports the proposed metabolic pathways of diisopropyl adipate. No two-generation reproduction study is available for diisopropyl adipate; however, the degree of concern for the lack of this study is low for the reasons provided in Unit III.D.2.

ii. There is no indication that diisopropyl adipate is a neurotoxic chemical. Although no neurotoxicity studies are available in the database, no clinical signs of neurotoxicity were observed in the available subchronic and chronic studies. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There was no evidence that diisopropyl adipate results in increased susceptibility in rats, mice or hamsters in the prenatal developmental studies

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to diisopropyl adipate in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by diisopropyl adipate.

*E. Aggregate Risks and Determination of Safety*

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, diisopropyl adipate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to diisopropyl adipate from food and water will utilize 1.9% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Diisopropyl adipate is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to diisopropyl adipate.



Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 14,400 for both adult males and females and 4,400 for children. Because EPA's level of concern for diisopropyl adipate is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Diisopropyl adipate is currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to diisopropyl adipate.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 16,600 for both adult males and females and 4,800 for children. Because EPA's level of concern for diisopropyl adipate is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in a 2 year rodent carcinogenicity study, diisopropyl adipate is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to diisopropyl adipate residues.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of diisopropyl adipate in or on any food commodities.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for diisopropyl adipate.

### *C. Revisions to Petitioned-For Tolerances*

Based upon review of the data supporting the petition, the proposed use patterns may result in applications of pesticides post-harvest. Therefore EPA believes a more appropriate exemption would be under 40 CFR 180.910. EPA has modified the exemption requested to include an exemption from the requirement of a tolerance for residues of diisopropyl adipate (CAS Reg. No. 6938-94-9) under 40 CFR 180.910 when

used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

## **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180. 910 for diisopropyl adipate (CAS Reg. No. 6938-94-9) when used as an inert ingredient (solvent) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

## **VII. Statutory and Executive Order Reviews**

This final rule establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

## **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 29, 2013.

Lois Rossi,  
*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.910 is amended by alphabetically adding the inert ingredient “Diisopropyl adipate” to the table to read as follows:

**§180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

<b>Inert ingredients</b>	<b>Limits</b>	<b>Uses</b>
* * *	* *	* *
Diisopropyl adipate (CAS Reg. No. 6938-94-9)	40% in mosquito control formulations	Solvent, co-solvent
* * *	* *	* *

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